Environment (JCCRER Agreement)
Data Access Agreement for Work to be Performed by Organizations of the MINZDRAV (Russian Ministry of Health; Federal Department for Medical, Biological and Extreme Problems) and MINATOM (Russian Ministry of Atomic Energy) under the Agreement Between the Government of the Russian Federation and the Government of the United States of America on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment (JCCRER Agreement)

Project 2.2

ESTIMATION OF THE RISK OF STOCHASTIC (CANCER) EFFECTS OF OCCUPATIONAL RADIATION EXPOSURE

INTRODUCTION

The purpose of this data access agreement is to ensure that Russian and American scientists working on projects under the Agreement Between the Government of the Russian Federation and the Government of the United States of America on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment (JCCRER Agreement) have equal access to all primary and original Russian and American data necessary to conduct the work described under Directions 1 and 2 of the JCCRER Agreement. Such access will ensure the highest quality of scientific research conducted in an atmosphere of mutual trust and cooperation.

GENERAL PROVISIONS

1. For the purposes of this agreement on data access, data is defined as all information, in whatever format or media, that is identified by the Principal Investigators and Directors of Participating Institutes as necessary to carry out the project.

2. Privacy statutes in Russia and the United States generally restrict access to data which includes personal identifiers. Individual data, however, is the basis of much of the research work of the JCCRER. Therefore, where necessary, adherence to these statutes will be ensured by substituting unique numerical identifiers which protect individual privacy while allowing analysis of individual and aggregate data.

3. Data covered by this access agreement include original or raw data, compiled data created before these projects were begun, and second generation or summarized data and information compiled according to project requirements. The specific project agreement provisions will specify the actual data which fall under each of these categories. Appropriate access to all these data must be ensured; however, original or raw data, and compiled data created before

these projects were begun remain the property of that organization and that country where the data were obtained and are currently maintained.

4. Secondary data created as part of JCCRER projects, which are a joint scientific product, will be jointly owned by the Russian and the American institutions participating in the project. Each project will determine what is a scientific product of the collaboration and therefore subject to joint ownership.

5. Project participants have the right to appropriate access to original, compiled and secondary data on the territory of the organization which owns and maintains the data.

6. The specific project agreement provisions will identify the kind and extent of unpublished primary, compiled and secondary data that may be transferred out of the country of ownership to achieve specific project goals such as technical analyses, modeling, etc. at the home institution of researchers. When such data transfers occur, they must also be approved in writing by the Director of the institute or organization to which the data belong. Transferred data cannot be used for purposes other than those specified by the agreement, even after the project is completed or the researcher is no longer associated with the JCCRER. In cases where such data are transferred to people who are not participants in the project for the purposes of furthering the project, the same conditions and limitations on use of data apply. Such transfers will be carefully scrutinized.

7. No transfers, publications, presentations, press releases or any other form of communication to the outside world regarding details of the unpublished data or the unpublished results of studies conducted under the authority of the JCCRER will be made without the written consent, and participation of the institutions maintaining the data sets and the scientists involved in the research. Any agreement to make data publicly available must be approved by the Directors of organization performing the research. Scientists and specialists participating as current members of the JCCRER Joint Committee, Executive Committee and Scientific Review Groups have a right to review data and unpublished results of studies as appropriate to their responsibilities but are similarly bound by the restrictions on communication as described in this paragraph.

8. Dissemination of scientific results, in the form of presentations at scientific meetings and publications in referred journals, is regarded as an essential product of the JCCRER work. To ensure that such communications take place while complying with the requirements of the participating institutions and funding agencies, procedures will be developed for the expeditious review and approval of such communication requests from the principal investigators.

9. Data published in the open, peer-reviewed literature shall be referenced and used according to generally understood and accepted conventions of scientific conduct; it is expected that proper reference and credit to the origin of the published material will be made.

10. After the publication of reports, third parties may request access to unpublished study data that does not contain individual identifiers, in order to conduct independent analyses. Third parties are defined as experts in the fields of radiation health effects and dosimetry who are not part of any JCCRER project. Procedures will be developed for requesting and approving such third party access to primary data.

PROJECT 2.2 DATA ACCESS AGREEMENT: SPECIFIC PROVISIONS

INTRODUCTION

The Mayak nuclear facility, which began operations in 1948 and which is managed by the Mayak Production Association (PA), has nuclear reactors, a radiochemical plant, and a plutonium production facility. During the first decade of Mayak's operation, workers at the plants were exposed to doses of external gamma radiation that were substantially higher than current occupational dose limits, and were also exposed to inhaled plutonium at levels much higher than those considered permissible today. Objectives of epidemiologic studies of workers at the Mayak facility are to provide estimates of carcinogenic risk from protracted external exposure at high doses, from occupational exposure to females, and from exposure from internally deposited plutonium. Data from studies of workers elsewhere, including the United States, United Kingdom, and Canada are not adequate for addressing these issues.

This project complements ongoing work by other organizations, particularly in expanding a National Cancer Institute project on dose response analysis, based on external doses, to include analysis of effects of internally deposited plutonium. The project also includes expansion of the cohort to include workers at auxiliary plants with little or no occupational radiation exposure.

PERSONS WITH RIGHTS OF ACCESS TO PROJECT 2.2 DATA

In addition to those specified in item 7 of the General Provisions, above, as having access to the data, access to original, compiled and secondary data is granted to the Russian and American scientists participating in Project 2.2. This access is granted on the premises of Branch No. 1 of the First Institute of Biophysics (FIB-1) at Laboratory No. 5.

DATA COVERED BY THIS ACCESS AGREEMENT

The data covered by this access agreement includes all information in any format, which contains personal identifying data, as well as information on place of work, occupational history, doses of occupational radiation exposure, and causes of death of Mayak workers hired in 1948-1972. It also includes all data, data files, and data bases that may be created in the future in the course of fulfillment of agreed upon work for Project 2.2. Additions to data bases and data files are intended to be done within the context of existing or future software and systems to be located at FIB-1.

Original Data

Original data is all primary information in any format on Mayak workers, including the following:

1. Records maintained by the Mayak PA including personnel records, dosimetry books stored in the archives of the Mayak Radiation Safety Service, and medical records in worker clinics.
2. Data from the Plutonium Registry managed by Dr. Valentin Khokhyrakov at FIB-1
3. Records from address bureaus in local and other municipalities, vital statistics bureaus, pathology departments, the Medico-Sanitary Department of Ozersk, and the Russian Federation Ministry of Atomic Energy.

Compiled Data Created Before the Beginning of Project 2.2

Relevant data have been extracted from these records listed above and individual data cards prepared for each person who began working at the atomic reactors, radiochemical and plutonium production plants of the Mayak PA between January 1, 1948 and December 31, 1972. These data cards are the property of FIB-1 laboratory No. 5, where these data are kept and maintained. Only laboratory No. 5 staff members have access to primary personal identifying information.

Selected information from the individual data cards described above has been computerized, and the resulting database comprises the Mayak Worker Registry. This database includes demographic data, major plant of employment, dates of employment, annual external radiation doses, plutonium body burdens, doses to the lung, liver, and bone from plutonium deposition, vital status and cause of death. Privacy is protected by identifying study subjects with unique individual identification numbers, which will allow analysis of individual and grouped data.

Data Compiled for this Project

It is expected that the Mayak Worker Registry, referred to above, will be improved and expanded as a result of research conducted under project 2.2. For example, selected workers at auxiliary plants will be added to expand the low dose portion of the data. Improvements in dosimetry are also proposed and will eventually be added to the database. In addition, special files are prepared for the purpose of statistical analyses. These files often include person-years and numbers of deaths categorized by variables including demographic factors (such as sex, age, and calendar period), plant of employment, and various measures of radiation exposure. Such files would not include personal identifiers.

Any data developed in the U.S. will be provided to Russian investigators and will be added to these altered or future data bases, which will be subject to joint ownership as described in item 7 of the General Provisions, above. During the project period, however, the full data bases will not be copied and maintained separately in the U.S.

DATA THAT MIGHT BE REMOVED FROM THE COUNTRY OF ORIGIN

Unpublished, summarized data may be sent or taken to the U.S. for the purpose of finishing and submitting joint progress reports to financial sponsors or for submitting joint publications to peer-reviewed scientific journals.

APPROVALS

Nina Koshurnikova		Principal Investigator, Russia
Ethel Gilbert	Ethel Gilbert	Principal Investigator, United States
Sergei A. Romanov		Director, Branch No. 1 of the First Institute of Biophysics
Mikhail F. Kiselev		Deputy Department Head, Federal Department for Medical, Biological and Extreme Problems, Ministry of Health of the Russian Federation
Frank Hawkins	11/30/98	Office Director, Office of International Health Programs, U.S. Department of Energy